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09/684,017	01/08/2001	James F. Zucherman	KLYC 1000USN SRM	9622

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FLIESLER DUBB MEYER & LOVEJOY, LLP
FOUR EMBARCADERO CENTER
SUITE 400
SAN FRANCISCO, CA 94111

[REDACTED] EXAMINER

WOO, JULIAN W

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

3731

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/684,017	ZUCHERMAN ET AL.
	Examiner	Art Unit
	Julian W. Woo	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 October 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 90-98, 101-103, 105-108, 112 and 113 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 90-98, 101-103, 105-108, 112 and 113 is/are rejected.

7) Claim(s) 99, 100 and 104 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 90-92, 95, 96 and 101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5, 16, 25, and 26 of U.S. Patent No. 6,149,652. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim a method for stabilizing a spinous process relative to another spinous process, where the method includes introducing between the spinous processes a device which conforms in situ to the shape of at least one of the spinous processes, where the device is filled with a fluid, like a shock absorber, in order to distract and/or maintain distraction between the spinous processes; and where the device includes a flexible wall and a cavity filled with a material.

3. Claims 93 and 94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 3 of U.S.

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Patent No. 6,149,652 in view of U.S. Patent No. 5,549,679. Claims 2 and 3 of U.S. Patent No. 6,149,652 disclose subject matter substantially as claimed in the application's claims 93 and 94, but do not disclose a device with flexible walls and a sealable cavity. U.S. Patent No. 5,549,679 teach a fillable device (40) with flexible walls and a sealable cavity (see, e.g., figs. 17-19 for sealing means 60, 58, and 62). Thus, it would have been obvious to one having ordinary skill in the art to modify the device of U.S. Patent No. 6,149,652, so that it has a sealable cavity. A sealing means would prevent the loss of material from a filled device, so that the device maintains its desired shape.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 90-92, 95-98, and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Breard (5,011,484). With respect to claims 90-92, Breard discloses, in col. 2, lines 9-15; col. 3, line 14-31; col. 4, lines 10-28; and figures 1-5; a method for

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stabilizing a spinous process (A) relative to another spinous process, where a device (1) is introduced between and conformed to the processes. Also with respect to claims 91, 92, and 98, the pre-formed device is made of an elastic or resilient material with a shape memory (polytetrafluoroethylene or PTFE) and has a cantilevered configuration (at lips, 4 and 5), which can be made to conform to a process in-situ with the artificial ligament (L). With respect to claim 101 the device has cavities (2, 3, 8) fillable with materials, such as the artificial ligament or portions of the spinous processes. With respect to claims 95-97: Since the device is made of PTFE, it inherently provides shock-absorbing, compressible surfaces, which dampen motion of the processes and spread forces in contact with the device.

6. Claims 102, 103, 105, 106, and 108 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich (5,549,679). Kuslich discloses, in figure 12 and in col. 9, lines 41-52, the introduction of a device (146) in the vicinity of or about spinous processes, where the device has a first, loose configuration and a second, rigid configuration; and where the device is not connected to the processes.

7. Claims 90, 91, 112, and 113 are rejected under 35 U.S.C. 102(e) as being anticipated by Voydeville (5,609,634). Voydeville disclose, in figures 7 and 8 and in col. 3, line 31 to col. 4, line 4, a method for stabilizing a spinous process relative to another spinous process, where the method includes introducing between the spinous process a device (3 combined with 6) adapted to conform to a shape of a spinous process and distract apart the spinous processes.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 105 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich. Kuslich discloses the invention substantially as claimed, but does not specifically disclose an introduction tool in the method; nor does Kuslich disclose a device with a first temperature in a first configuration and a second temperature in a second configuration. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply an introduction tool (e.g., forceps) to insert an adjust Kuslich's device in a patient. An introduction tool provides a convenient means to manipulate the device in a confined surgical environment. Also, it would be obvious to render the device with a first temperature in a first configuration and a second temperature in a second configuration. The first temperature of the loose,

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device materials (see col. 12, lines 16-23) can be room temperature or at a refrigerated temperature before its introduction into a patient, while the second temperature of rigidified materials can be body temperature after introduction of the device in a patient.

Allowable Subject Matter

10. Claims 99, 100, and 104 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a method of stabilizing a spinous process relative to another spinous process, where the method includes the introduction of a device between the processes, and where the device is made of a material which changes shape or is reconfigured, while it is between the processes.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

12. Applicant's arguments filed on October 25, 2002 have been fully considered but they are not persuasive with respect to claims 90-92, 95-98, 101-103, and 105-108. Applicant's arguments with respect to claims 90-96, 101, 112, and 113 have been considered but are moot in view of the new ground(s) of rejection. With respect to

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arguments regarding the rejections over Breard: Breard does teach a device conformable in situ (i.e., at implantation of the device in a body) to the shape of a spinous process. Col. 2, lines 14 and 15 disclose a device having a groove width, which "conform[s] to the naturally tapering shape of the spine." Additionally, Breard discloses a device made of a plastic material such as PTFE, which not only has a low friction coefficient, it is a resilient and tough polymer that inherently has a shape memory and acts as shock absorber when impacted.

With respect to arguments regarding rejections over Kuslich: Kuslich does provide a device that is "relative" to a spinous process, where the device is positioned in relation to or near a spinous process, even between two spinous processes.

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Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.



Julian W. Woo
Patent Examiner

December 27, 2002